

§ 74.3602

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Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[55 FR 22898, June 5, 1990]

§ 74.3602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* (1) The color additive, D&C Violet No. 2, may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) D&C Violet No. 2 may be safely used for coloring sutures for use in surgery subject to the following conditions:

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring copolymers of 90 percent glycolide and 10 percent L-lactide synthetic absorbable sutures for use in general and ophthalmic surgery; and

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery.

(iii) At a level not to exceed 0.25 percent by weight of the suture material for coloring poliglecaprone 25 (ε-caprolactone/glycolide copolymer) synthetic absorbable sutures for use in general surgery.

(iv) At a level not to exceed 0.1 percent by weight of the suture material for coloring poly(ε-caprolactone) absorbable sutures for use in general surgery.

(v) At a level not to exceed 0.2 percent by weight of the suture material for coloring glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for use in general surgery.

(vi) At a level not to exceed 0.2 percent by weight of the suture material for coloring absorbable sutures pre-

pared from homopolymers of glycolide for use in general surgery.

(3) The color additive, D&C Violet No. 2, may be safely used for coloring polymethylmethacrylate intraocular lens haptics at a level not to exceed 0.2 percent by weight of the haptic material.

(4) The color additive, D&C Violet No. 2, may be safely used for coloring absorbable meniscal tacks made from poly (L-lactic acid) at a level not to exceed 0.15 percent by weight of the tack material.

(5) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical devices in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 19722, May 27, 1987, as amended at 55 FR 18868, May 7, 1990; 58 FR 60109, Nov. 15, 1993; 59 FR 11720, Mar. 14, 1994; 63 FR 20098, Apr. 23, 1998; 64 FR 32805, June 18, 1999; 65 FR 46344, July 28, 2000]

§ 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.